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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC.

Plaintiff,

v.

ACTAVIS ELIZABETH LLC, ACTAVIS, INC., WATSON LABORATORIES, INC. – FLORIDA, WATSON PHARMA, INC., WATSON PHARMACEUTICALS, INC., and INCEPTA PHARMACEUTICALS CO. LTD.

Defendants.

CIVIL ACTION NO: 3:12-cv-01358-JAP-TJB

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Depomed, Inc., complains against defendants Actavis Elizabeth LLC and Actavis Inc. (collectively "Actavis"), Watson Laboratories, Inc. – Florida, Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. (collectively "Watson") and Incepta Pharmaceuticals Co. Ltd. ("Incepta") as follows:

THE PARTIES

- 1. Plaintiff Depomed, Inc. ("Depomed"), is a corporation organized under the laws of California, having its principal place of business in Menlo Park, California.
- 2. Upon information and belief, Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.
- 3. Upon information and belief, Actavis Elizabeth LLC is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. On information and belief, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis Inc. On information and belief, Actavis Elizabeth LLC's preparation and submission of ANDA No. 203611 was done collaboratively with, and for the benefit of, Actavis Inc. On information and belief, Actavis Elizabeth LLC is the alter ego of Actavis Inc. where a unity of interest and ownership exists between Actavis Elizabeth LLC and Actavis Inc. such that separate personalities of the two do not in reality exist.
- 4. Upon information and belief, Watson Laboratories, Inc. Florida ("Watson Labs") is a corporation organized and existing under the laws of the State of Florida having a place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Watson Labs is in the business of developing and manufacturing generic pharmaceutical products for the U.S. market and is a wholly owned subsidiary of Watson Pharmaceuticals, Inc. On information and belief, Watson Labs's preparation and submission of ANDA No. 203625 was done collaboratively with, and for the benefit of, Watson Pharmaceuticals, Inc. On information and belief, Watson Labs is the alter ego of Watson Pharmaceuticals, Inc. where a unity of interest and ownership exists between Watson Labs and Watson Pharmaceuticals, Inc. such that separate personalities of the two do not in reality exist.
- 5. Upon information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of Delaware with principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson

Pharma is in the business of distributing and/or selling generic pharmaceutical products in the United States market, including products made by Watson Labs and is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. On information and belief, Watson Pharma is the alter ego of Watson Pharmaceuticals, Inc. where a unity of interest and ownership exists between Watson Pharma and Watson Pharmaceuticals, Inc. such that separate personalities of the two do not in reality exist.

- 6. Upon information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada with corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson Pharmaceuticals is in the business of developing, manufacturing, and/or marketing pharmaceutical products in the United States, including in this judicial district, through at least the actions of its subsidiaries Watson Labs and Watson Pharma.
- 7. Upon information and belief, Watson Pharmaceuticals, Watson Pharma and Watson Labs share certain common employees, officers and directors.
- 8. Upon information and belief, Incepta Pharmaceuticals Co. Ltd. ("Incepta") is a Bangladeshi company located at 40 Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1209, Bangladesh. On information and belief, Incepta is in the business of manufacturing and marketing pharmaceutical products; it manufactures more than 600 products and markets its products globally.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the patent laws of the United States (Title 35 of the United States Code) and arising from Actavis, Watson and Incepta each filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Depomed's product Gralise® prior to the expiration of U.S. Patent Nos. 6,340,475, 6,488,962, 6,635,280,

6,723,340, 7,438,927 and 7,731,989. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

- 10. This Court has personal jurisdiction over Actavis because, among other things, Actavis resides in New Jersey, conducts business in the State of New Jersey, has availed itself of the rights and benefits under New Jersey law, and has engaged in substantial and continuous contacts in the State of New Jersey. Moreover, Actavis has a past practice of consenting to personal jurisdiction in this Court for other litigation matters. For example, Actavis consented to personal jurisdiction in *Shire LLC and Shire Development, Inc. v. Actavis Elizabeth LLC et al.*, Civil Action No. 2:11-cv-04053 and *Sanofi-Aventis U.S. LLC et al. v. Actavis Inc. et al.*, Civil Action No. 2:10-cv-02795.
- 11. This Court has personal jurisdiction over Watson Labs, Watson Pharmaceuticals, and Watson Pharma because, *inter alia*, they have purposely availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here. On information and belief, Watson Pharmaceuticals, Watson Labs, Watson Pharma have had persistent, systematic and continuous contacts with New Jersey as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged. Watson maintains executive offices in New Jersey, conducts business in the State of New Jersey, and has a past practice of consenting to personal jurisdiction in this Court for other litigation matters. For example, Watson has consented to personal jurisdiction in *Hoffmann-La Roche Inc.* v. Watson Laboratories, Inc. et al., Civil Action No. 2:10-cv-06206 and Astrazeneca et al. v. Watson Laboratories, Inc., Civil Action 1:11-cv-03626.
- 12. Watson Labs, Watson Pharmaceuticals, and Watson Pharma directly or through an agent, including each other, regularly do or solicit business in New Jersey, engage in persistent courses of conduct in New Jersey, and/or derive substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in New Jersey.
- 13. Watson Labs, Watson Pharmaceuticals, and Watson Pharma are agents of each other and/or work in concert with each other and/or other direct and indirect subsidiaries of

Watson Pharmaceuticals with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceuticals products throughout the United States, including in this district.

- 14. Upon information and belief, Watson Pharmaceuticals, Watson Labs and Watson Pharma operate in whole or in part from one or more shared facilities in New Jersey.
- 15. Upon information and belief, and according to its website, http://www.watson.com, Watson Pharmaceuticals organizes its operations by division—Global Generics, Global Brands and ANDA Distribution—rather than by subsidiary, and reports its financial results to investors by reference to its divisions, rather than its subsidiaries.
- 16. Upon information and belief, the Global Generics Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on the concerted efforts of Watson Labs, Watson Pharmaceuticals, and Watson Pharma.
- 17. Upon information and belief, Watson Pharmaceuticals, Watson Labs and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson's Generic division.
- 18. Upon information and belief, Watson Pharmaceuticals consolidates its financial results and does not provide separate financial reports for each Watson subsidiary.
- 19. Upon information and belief, neither Watson Pharma nor Watson Labs maintains an independent website; instead Watson Pharmaceuticals maintains a single website for all Watson entities, which is located at http://www.watson.com.
- 20. Upon information and belief, Watson Pharmaceuticals, and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 203625, the ANDA at issue in this litigation. For instance, by letter dated February 13, 2012, Watson Labs directed Depomed to send any correspondence or requests for confidential access concerning ANDA No. 203625 to its "in-house counsel," Mr. G. Michael

Bryner, who is registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

- 21. Watson Pharmaceuticals' website states that its Global Generics Division has a U.S. Portfolio of more than 160 generic prescriptions pharmaceutical product families (including products for which Watson Labs is the named ANDA applicant); that it filed over 30 new ANDAs with the FDA in 2011; and that it filed more than 175 applications globally in 2011.
- 22. Upon information and belief, Watson Labs is the named applicant on ANDAs for numerous generic drugs, including many that are actively manufactured, sold and used in New Jersey and elsewhere in the United States.
- 23. Upon information and belief, Watson Pharma is the distributor of drugs for which Watson Labs is the named applicant in the FDA's Approved Drug Product List. Upon information and belief, Watson Pharma, acting as the agent of Watson Labs and Watson Pharmaceuticals, markets and sells Watson's drug products in New Jersey and elsewhere in the United States.
- 24. Upon information and belief, various drugs for which Watson Labs is the named ANDA applicant are distributed by Watson Pharma and are available at retail pharmacies in New Jersey.
- 25. Upon information and belief, Watson Pharmaceuticals and/or Watson Labs earn revenue from the distribution in New Jersey by Watson Pharma of generic pharmaceutical products that are manufactured by Watson Labs or for which Watson Labs is named applicant on approved ANDAs.
- 26. Watson Pharmaceuticals' website provides links to its distribution network where physicians, pharmacies, and distributors in New Jersey and elsewhere are able to directly order Watson's products, including products manufactured by Watson Labs and products for which Watson Labs is the named ANDA applicant, via Watson Pharmaceutical's internet distribution network.

- Watson Labs will manufacture, market, and/or sell within the United States the generic 300 mg and 600 mg Gabapentin extended release tablets described in Watson's ANDA no. 203625 if FDA approval is granted. If ANDA no. 203625 is approved, the generic 300 mg and 600 mg Gabapentin extended release tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.
- 28. This Court has personal jurisdiction over Incepta because Depomed's claims arise under federal law, Incepta, upon information and belief, is not subject to jurisdiction in any state's court of general jurisdiction and the exercise of jurisdiction over Incepta comports with due process because Incepta purposely directed activities at the United States and availed itself of the laws of the United States by submitting an ANDA with the FDA to obtain approval to engage in the commercial manufacture, importation, use and/or sale of 300mg and 600mg gabapentin oral tablets and Depomed's claims arise out of this activity. Moreover, Incepta has availed itself of the rights and benefits under New Jersey law by purposely choosing the law of the State of New Jersey to govern the Offer of Confidential Access that Incepta has provided to Plaintiff in its Paragraph IV certification letter.
 - 29. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400.

THE PATENTS-IN-SUIT

- 30. On January 22, 2002, United States Patent No. 6,340,475 (the "475 Patent") entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode" issued to Depomed as assignee of the inventors. (A copy of the '475 Patent is attached as Exhibit 1.)
- 31. On December 3, 2002, United States Patent No. 6,488,962 (the "'962 Patent") entitled "Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral

Dosage Forms" issued to Depomed as assignee of the inventors. (A copy of the '962 Patent is attached as Exhibit 2.)

- 32. On October 21, 2003, United States Patent No. 6,635,280 (the "280 Patent") entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode" issued to Depomed as assignee of the inventors. (A copy of the '280 Patent is attached as Exhibit 3.)
- 33. On April 20, 2004, United States Patent No. 6,723,340 (the "340 Patent") entitled "Optimal Polymer Mixtures for Gastric Retentive Tablets" issued to Depomed as assignee of the inventors. (A copy of the '340 Patent is attached as Exhibit 4.)
- 34. On October 21, 2008, United States Patent No. 7,438,927 (the "'927 Patent") entitled "Methods of Treatment Using a Gastric Retained Gabapentin Dosage" issued to Depomed as assignee of the inventors. (A copy of the '927 Patent is attached as Exhibit 5.)
- 35. On June 8, 2010, United States Patent No. 7,731,989 (the "'989 Patent') entitled "Gastric Retained Gabapentin Dosage Form" issued to Depomed as assignee of the inventors. (A copy of the '989 Patent is attached as Exhibit 6.)

GRALISE®

- 36. Depomed holds approved New Drug Application No. 022544 (the "Depomed NDA") for gabapentin extended-release tablets in 300 and 600 mg dosage strengths, which are sold under the trade name Gralise[®].
- 37. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '475, '962, '280. '340, '927 and '989 Patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Gralise® in the 300 mg dosage.
- 38. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '475, '962, '280. '340, '927 and '989 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Gralise[®] in the 600 mg dosage.

ACTAVIS'S ANDA

- 39. On information and belief, Actavis submitted ANDA No. 203611 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of Gabapentin Extended-Release Tablets in the 300 and 600 mg dosage strengths. The Gabapentin Extended-Release Tablets described in the Actavis ANDA are herein referred to as the "Actavis Products," the 300 mg dosage strength is referred to as the "Actavis 300 mg Product," and the 600 mg dosage strength is referred to as the "Actavis 600 mg Product."
- 40. On information and belief, the Actavis ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of the Actavis Products and Gralise®.
- 41. Depomed received from Actavis a letter, dated January 19, 2012, stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '475, '280, '989, '927, '340, and '962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Products (the "Actavis Notification Letter"). (A true and correct copy of the Actavis Notification Letter is attached hereto as Exhibit 7.)

WATSON'S ANDA

- 42. On information and belief, Watson submitted ANDA No. 203625 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of Gabapentin Tablets in the 300 and 600 mg dosage strengths. The Gabapentin Tablets described in the Watson ANDA are herein referred to as the "Watson Products," the 300 mg dosage strength is referred to as the "Watson 300 mg Product," and the 600 mg dosage strength is referred to as the "Watson 600 mg Product."
- 43. On information and belief, the Watson ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of the Watson Products and Gralise®.

44. Deponded received from Watson a letter, dated February 13, 2012, stating that Watson had included a certification in the Watson ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '475, '280, '989, '927, '340, and '962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Watson Products (the "Watson Notification Letter"). (A true and correct copy of the Watson Notification Letter is attached hereto as Exhibit 8.)

INCEPTA'S ANDA

- 45. On information and belief, Incepta submitted ANDA No. 203643 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of gabapentin oral tablets in the 300 and 600 mg dosage strengths. The gabapentin oral tablets described in the Incepta ANDA are herein referred to as the "Incepta Products," the 300 mg dosage strength is referred to as the "Incepta 300 mg Product," and the 600 mg dosage strength is referred to as the "Incepta 600 mg Product."
- 46. On information and belief, the Incepta ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of the Incepta Products and Gralise®.
- 47. Depomed received from Incepta a letter, dated February 27, 2012, stating that Incepta had included a certification in the Incepta ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '475, '280, '989, '927, '340, and '962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Watson Products (the "Incepta Notification Letter"). (A true and correct copy of the Incepta Notification Letter is attached hereto as Exhibit 9.)

FIRST CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '475 Patent by Actavis)

48. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.

- 49. On information and belief, Actavis has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '475 Patent.
- 50. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 51. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '475 Patent, would further infringe the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 52. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '475 Patent.
 - 53. Plaintiff has no adequate remedy at law.
- 54. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SECOND CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '475 Patent by Watson)

- 55. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 56. On information and belief, Watson has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Watson seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products prior to the expiration of the '475 Patent.

- 57. Watson has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Watson Products in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 58. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products into the United States during the term of the '475 Patent, would further infringe the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 59. Plaintiff will be substantially and irreparably harmed if Watson is not enjoined from infringing the '475 Patent.
 - 60. Plaintiff has no adequate remedy at law.
- 61. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

THIRD CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '475 Patent by Incepta)

- 62. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 63. On information and belief, Incepta has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '475 Patent.
- 64. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 65. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '475 Patent, would further infringe the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 66. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the '475 Patent.
 - 67. Plaintiff has no adequate remedy at law.
- 68. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FOURTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '962 Patent by Actavis)

- 69. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 70. On information and belief, Actavis has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '962 Patent.
- 71. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 72. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '962 Patent, would further infringe the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 73. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '962 Patent.
 - 74. Plaintiff has no adequate remedy at law.
- 75. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FIFTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '962 Patent by Watson)

- 76. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 77. On information and belief, Watson has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Watson seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products prior to the expiration of the '962 Patent.
- 78. Watson has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Watson Products in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 79. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products into the United States during the term of the '962 Patent, would further infringe the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 80. Plaintiff will be substantially and irreparably harmed if Watson is not enjoined from infringing the '962 Patent.
 - 81. Plaintiff has no adequate remedy at law.
- 82. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SIXTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '962 Patent by Incepta)

- 83. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 84. On information and belief, Incepta has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '962 Patent.
- 85. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 86. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '962 Patent, would further infringe the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 87. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the '962 Patent.
 - 88. Plaintiff has no adequate remedy at law.
- 89. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SEVENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '280 Patent by Actavis)

90. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.

- 91. On information and belief, Actavis has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '280 Patent.
- 92. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 93. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '280 Patent, would further infringe the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 94. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '280 Patent.
 - 95. Plaintiff has no adequate remedy at law.
- 96. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

EIGHTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '280 Patent by Watson)

- 97. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 98. On information and belief, Watson has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Watson seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products prior to the expiration of the '280 Patent.

- 99. Watson has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Watson Products in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 100. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products into the United States during the term of the '280 Patent, would further infringe the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 101. Plaintiff will be substantially and irreparably harmed if Watson is not enjoined from infringing the '280 Patent.
 - 102. Plaintiff has no adequate remedy at law.
- 103. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

NINTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '280 Patent by Incepta)

- 104. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 105. On information and belief, Incepta has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '280 Patent.
- 106. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 107. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '280 Patent, would further infringe the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 108. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the '280 Patent.
 - 109. Plaintiff has no adequate remedy at law.
- 110. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

TENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '340 Patent by Actavis)

- 111. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 112. On information and belief, Actavis has infringed the '340 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '340 Patent.
- 113. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 114. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '340 Patent, would further infringe the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 115. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '340 Patent.
 - 116. Plaintiff has no adequate remedy at law.
- 117. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ELEVENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '340 Patent by Watson)

- 118. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 119. On information and belief, Watson has infringed the '340 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Watson seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products prior to the expiration of the '340 Patent.
- 120. Watson has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Watson Products in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 121. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products into the United States during the term of the '340 Patent, would further infringe the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 122. Plaintiff will be substantially and irreparably harmed if Watson is not enjoined from infringing the '340 Patent.
 - 123. Plaintiff has no adequate remedy at law.
- 124. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

TWELFTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '340 Patent by Incepta)

- 125. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 126. On information and belief, Incepta has infringed the '340 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '340 Patent.
- 127. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 128. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '340 Patent, would further infringe the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 129. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the '340 Patent.
 - 130. Plaintiff has no adequate remedy at law.
- 131. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

THIRTEENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '927 Patent by Actavis)

132. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.

- 133. On information and belief, Actavis has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '927 Patent.
- 134. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '927 patent under 35 U.S.C. §§ 271 (b) and/or (c).
- 135. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '927 Patent, would further infringe the '927 Patent under 35 U.S.C. §§ 271 (b) and/or (c).
- 136. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '927 Patent.
 - 137. Plaintiff has no adequate remedy at law.
- 138. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FOURTEENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '927 Patent by Watson)

- 139. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 140. On information and belief, Watson has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Watson seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products prior to the expiration of the '927 Patent.

- 141. Watson has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Watson Products in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 142. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products into the United States during the term of the '927 Patent, would further infringe the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 143. Plaintiff will be substantially and irreparably harmed if Watson is not enjoined from infringing the '927 Patent.
 - 144. Plaintiff has no adequate remedy at law.
- 145. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FIFTEENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '927 Patent by Incepta)

- 146. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 147. On information and belief, Incepta has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '927 Patent.
- 148. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 149. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '927 Patent, would further infringe the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 150. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the '927 Patent.
 - 151. Plaintiff has no adequate remedy at law.
- 152. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285

SIXTEENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '989 Patent by Actavis)

- 153. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 154. On information and belief, Actavis has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '989 Patent.
- 155. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 156. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '989 Patent, would further infringe the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 157. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '989 Patent.
 - 158. Plaintiff has no adequate remedy at law.
- 159. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SEVENTEENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '989 Patent by Watson)

- 160. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 161. On information and belief, Watson has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, by which Watson seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Watson Products prior to the expiration of the '989 Patent.
- 162. Watson has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Watson Products in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 163. Watson's commercial manufacture, use, offer to sell, or sale of the Watson Products within the United States, or importation of the Watson Products into the United States during the term of the '989 Patent, would further infringe the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 164. Plaintiff will be substantially and irreparably harmed if Watson is not enjoined from infringing the '989 Patent.
 - 165. Plaintiff has no adequate remedy at law.
- 166. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

EIGHTEENTH CAUSE OF ACTION

(Infringement and Declaratory Judgment of Infringement of the '989 Patent by Incepta)

- 167. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-47.
- 168. On information and belief, Incepta has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '989 Patent.
- 169. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 170. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '989 Patent, would further infringe the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 171. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the '989 Patent.
 - 172. Plaintiff has no adequate remedy at law.
- 173. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against defendants Actavis Elizabeth LLC and Actavis Inc. ("Actavis"), Watson Laboratories, Inc. – Florida, Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. ("Watson"), and Incepta Pharmaceuticals Co. Ltd. ("Incepta"), and respectfully requests the following relief:

- 1. A judgment that the '475, '962, '280, '340, '927 and '989 Patents have been infringed by Actavis;
- 2. A judgment that the '475, '962, '280, '340, '927 and '989 Patents have been infringed by Watson;
- 3. A judgment that the '475, '962, '280, '340, '927 and '989 Patents have been infringed by Incepta;
- 4. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Actavis, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Actavis Products within the United States, or importing the Actavis Products into the United States, prior to the expiration of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 5. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Watson, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Watson Products within the United States, or importing the Watson Products into the United States, prior to the expiration of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 6. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Incepta, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Incepta Products within the United States, or importing the Incepta Products into the United States, prior to the expiration of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 7. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203611 under § 505(j) of the Federal Food, Drug and Cosmetic

- Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 8. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203625 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 9. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203643 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 10. A judgment declaring and enjoining Actavis, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Actavis Products within the United States, or importing the Actavis Products into the United States, prior to the expiration dates of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 11. A judgment declaring and enjoining Watson, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Watson Products within the United States, or importing the Watson Products into the United States, prior to the expiration dates of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 12. A judgment declaring and enjoining Incepta, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Incepta Products within the United States, or importing the Incepta Products into the United States, prior to the expiration dates of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
- 13. If Actavis commercially manufactures, uses, offers to sell, or sells the Actavis Products within the United States, or imports the Actavis Products into the United States, prior to

the expiration of any of the '475, '962, '280, '340, '927 and/or '989 Patents, including any

extensions, a judgment awarding Plaintiff monetary relief together with interest;

14. If Watson commercially manufactures, uses, offers to sell, or sells the Watson

Products within the United States, or imports the Watson Products into the United States, prior to

the expiration of any of the '475, '962, '280, '340, '927 and/or '989 Patents, including any

extensions, a judgment awarding Plaintiff monetary relief together with interest;

15. If Incepta commercially manufactures, uses, offers to sell, or sells the Incepta

Products within the United States, or imports the Incepta Products into the United States, prior to

the expiration of any of the '475, '962, '280, '340, '927 and/or '989 Patents, including any

extensions, a judgment awarding Plaintiff monetary relief together with interest;

16. An award of damages together with interest, and a judgment that the damages so

adjudged be trebled pursuant to 35 U.S.C. §§ 283 and 284;

17. Judgment that this is an exceptional case and that Plaintiff be awarded its

attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

18. Costs and expenses in this action; and

19. Such other and further relief as the Court deems just and appropriate.

Dated: March 30, 2012

Respectfully submitted,

By: s/ Leda Dunn Wettre

Leda Dunn Wettre

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Attorneys for Plaintiff Depomed, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2012 I served the foregoing First Amended Complaint upon all counsel of record via CM/ECF.

<u>S/ Leda Dunn Wettre</u>Leda Dunn Wettre

Dated: March 30, 2012